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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,151	01/15/2002	Jurgen Strube	2234/50345	6157
23911	7590	10/06/2003	EXAMINER	
CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			GOLLAMUDI, SHARMILA S	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/937,151	STRUBE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 1/15/02.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2 and 4-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2 and 4-11 is/are rejected.
- 7) Claim(s) 8 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

Receipt of Information Disclosure Statement and Preliminary Amendment A received on January 15, 2002 is acknowledged. Claims 1-2 and 4-11 are included in the prosecution of this application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-2 and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 1 recites "the potentiating agent containing at least one of bound amino acids and free amino acids, which is vague and indefinite. It is unclear if the potentiating agent is has at least of each: a bound amino acids and free amino acids or the agent has either bound or free amino acids. Further clarification is requested.

Claim 4 recites that the agent is added as "accompanying material" which is vague and indefinite. It is unclear what accompanying material defines.

Claim 6-7 recites that the amino acids are produced by adding distilled alcohol; this is indefinite since it is unclear how alcohol adds amino acids. Further clarification is requested.

Claim 9 recites that natural air adds amino acids, which is vague and indefinite. It is unclear how air adds amino acids to a composition. If this were the case, then any pharmaceutical composition exposed to air would be potentiated.

Claim 10 recites water as the potentiating agent, which is indefinite. The chemical structure of water is H<sub>2</sub>O and this structure does not contain any amino acids. Claim 10 depends on claim 1 which clearly recites that the potentiating agent contains amino acids. Further clarification is requested.

Claim 11 recites lactose as the potentiating agent, which is indefinite. Lactose is a sugar and claim 11 depends on claim 1 that clearly recites that the potentiating agent contains amino acids. Further clarification is requested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-2, 4, and 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Cheng et al (6,200,569).**

Cheng et al disclose a composition and method for potentiating insulin activity. See abstract. The insulin potentiating agents are natural substances derived from an aqueous extract from plants or fungi. The composition contains the potentiating agent, a carrier, and other therapeutic agents. See column 3, lines 30-33 and examples.

\*Note since water is considered a potentiating agent by applicant and thus contains amino acids inherently, the prior art reads on instant claims.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**Claims 1-2 and 4 rejected under 35 U.S.C. 102(a) as being anticipated by**

**Porro et al (5,834,430).**

Porro et al disclose a method of potentiating antibiotics by co administering peptides with antibiotics. See abstract. The minimal effective peptide sequence for use as a potentiating agent comprises six to seven amino acids. See column 3.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-2, 4-7, and 9-10 are rejected under 35 U.S.C. 102() as being anticipated by Ho et al (5,665,359).**

HO et al disclose a method of lowering blood lipids by orally administering a Chinese fruit extract obtained from a water/alcohol extract. See column 6, claims, and examples. The extract is combined with other pharmaceutical compounds. See column 6, lines 55-60.

\*Note that applicant contends that fruit alcohol produces instant amino acids and thus the claims are rejected based upon inherency.

**Claims 1-2, 4, 9, and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Scanlin et al (5,948,681).**

Scanlin et al disclose method of treating respiratory diseases with a DNA complexed to polysine substituted with a sugar (lactose). See column 4, line 15. The reference disclose polysine substituted with lactose is superior to other substituted

polysines for effecting transfer of DNA into the primary airway epithelial cells. See column 10, lines 34-38.

\*Note that applicant contends that lactose has instant amino acids and thus the claims are rejected based upon inherency.

***Allowable Subject Matter***

Claim 8 is objected to as being dependent upon a rejected base claim 7, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

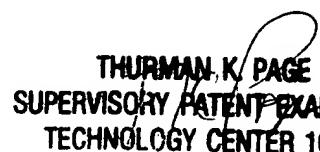
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG  


  
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